Sample Clinical Quality Management Regulatory File Review Tool

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. You may modify this as appropriate.)

Instructions: List the protocol number, the date range that is being reviewed and the date of the review. Once the review begins, check the appropriate boxes for each question listed in the criteria section. When the review is completed for all applicable documents, the QA reviewer will sign and date the form. Use the comments section for clarification and action on any "no" entries checked.

Site Name_____ **Site Number**_____

Name of Reviewer_____ **Date of Review**_____

Protocol Number_____**Version #**_____

Reviewed from (date)_____**to (date)**_____

		Present		
Document	***Criteria***	**Yes**	**No**	**N/A**
IRB/EC approval	Approval?			
Other Regulatory if applicable	Approval?			
	Informed Consent Approvals Present? Revision Approvals (if applicable) Present ?			
	Continuing Approvals Present?			
	Approvals for all protocol amendments present?			
	Communication and reports from IRB?EC and other regulatory bodies present?			
	Other written material given to participants Approvals Present? Revision Approvals (if applicable) Present ?			
DAIDS approvals	Is the DAIDS (RCC) approval for protocol registration present?			
Assurances	Is there a current assurance document from OHRP present and not expired?			
Safety Reports	Are EAE reports present?			
	Have these safety reports been submitted to IRB/IEC?			
	Are SAE, AE Local and Regional Reports present? Have these been submitted to the IRB/EC?			
Protocol	Is a current copy of the protocol on file?			

	Is the approved Master Informed Consent on file?			
	Are all previous versions on file?			
Case Report Forms	Are blank copies present? Are blank copies of all revisions present?			
1572/IOR agreement	Is there a 1572 (for IND studies), or an Investigator of Record Agreement on file?			
	Is the document current and accurate?			
	Is the PI CV on file and up to date?			
	PI CV/Biosketch on file, but not with Form 1572			
Other agreements (list)				
CVs;Biographical Sketches; Licenses	Present for all key personnel and current/updated?			
	Are GCP/HSP training certificates current and up-to-date?			
Financial Disclosure/Job description	Are financial disclosure forms for all key personnel present?			
	Are job descriptions for all personnel present?			
Site Monitoring Visit Reports	Are all visit reports present?			
Investigator Brochures	Are Investigator Brochures including revisions and applicable package inserts present for investigational products?			
Laboratory	Are laboratory certifications and normal ranges present for labs?			
	For other labs in protocol, are there any required certificates present? (include updates)			
Importation	Are FDA import permits present and not expired?			
Signature Logs	Is the signature key present for all individuals authorized to make entries in study records? Are delegation of responsibility lists present?			
Other Documents Reviewed:(list)				

Findings/Results of Review:

Comments/Corrective action to follow up on any "no" entries :

Problem	***Corrected by/date***

Signature of Reviewer_____ Date_____